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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/591,899 | 09/07/2006 | Masanori Somei | 1254-0323PUS1 | 7982 |
| 2292 | 7590 | 11/12/2010 | EXAMINER | |
| BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 | | | | PAGONAKIS, ANNA |
| ART UNIT | | PAPER NUMBER | | |
| | | | | 1628 |
| NOTIFICATION DATE | | | DELIVERY MODE | |
| 11/12/2010 | | | ELECTRONIC | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/591,899 | SOMEI ET AL. | |
| | Examiner | Art Unit | |
| | ANNA PAGONAKIS | 1628 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 October 2010.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 4-9 and 14-16 is/are pending in the application.
 4a) Of the above claim(s) 6-9 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 4,5 and 14-16 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

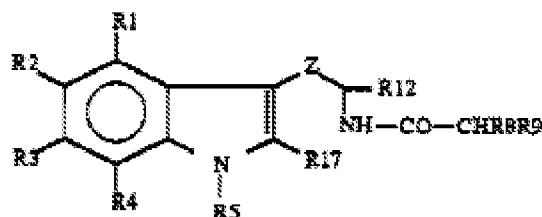
Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's payment and submission filed 10/8/2010, has been received and entered into the present application. Accordingly, prosecution has been reopened.

A reasonable and comprehensive search conducted by the Examiner determined that the prior art at the time of the present invention was such that it did not anticipate or render obvious the elected species. A search, however, did discover prior art that read on the claimed genus. Therefore, the prior art of the instant Office Action is drawn to the discovered species disclosed below. Specifically, the species election is being expanded to the following compound:



where on the above compound R1, R3 are each halogen R4 and R12 are each H, R17 is Br, R8, R9 and R5 is an alkyl group, R2 is a lower alkoxy and Z is an alkylene.

Applicant's arguments filed 10/26/2010 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Status of Claims

Claims 4-9 and 14-16 are currently pending.

Claims 6-9 remain withdrawn.

Claims 4-5 and 14-16 are currently under examination and the subject matter of the present Office Action.

New rejection:

Claim Rejections - 35 USC § 103

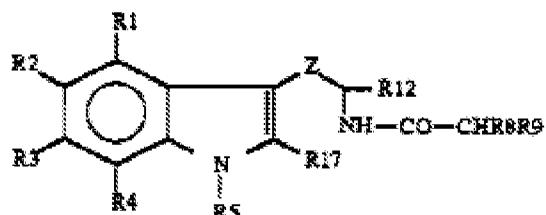
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-5 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fourtillan et al. (U.S. 5,763,471) in view of Patani et al. (Chem Rev., 1996, 96, 3146-76).

Fourtillan et al. teach the compound:



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where on the above compound R1, R3, R4 and R12 are H, R17 is Br, R8, R9 and R5 is an alkyl group, R2 is a lower alkoxy and Z is an alkylene. The compound can be used for the treatment of disorders associated with melatonin disorders in a pharmaceutical and cosmetic compositions (abstract).

The difference between the prior art compound and the compounds of the instant claims is that the substituents of R1 and R3 on the above compound are each a halogen atom, as recited in the instant claims.

Patani et al. teach that bioisosterism represents one approach used by the medicinal chemist for rational modification of lead compounds into safer and more clinically effective agents and further that the concept of bioisosterism is intuitive (page 3147, Introduction, column 1-2). Bioisosteric substitutions are well known in the art. Further, hydrogen and fluorine are isosteric (page 3149-3150). Specifically, replace H with a halogen such as F on an aromatic ring has shown to increase binding affinity and decrease the IC₅₀ values in the prior art (page 3149, Figure 2).

One of ordinary skill in the art would have found it *prima facie* obvious at the time of the invention to substitute a halogen such as fluorine or bromine over a hydrogen. One would have been motivated to derive the instantly claimed compound from those of the prior art because of the expectation that structurally similar compounds would possess similar activity (i.e. treatment of melatonin associated disorders such as osteoporosis) and to produce a more clinically effective agent, per Patani et al.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 7am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Brandon J Fetterolf/

Supervisory Patent Examiner, Art Unit 1628